



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Tongtong Wang and Chaitanya S. Bangur
Application No. : 09/519,642
Filed : March 6, 2000
For : COMPOSITIONS AND METHODS FOR THERAPY AND
DIAGNOSIS OF LUNG CANCER

Examiner : Michael L. Borin
Art Unit : 1631
Docket No. : 210121.478C4
Date : February 27, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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RESPONSE UNDER 37 C.F.R. § 1.111

Commissioner for Patents:

In response to the Office Action dated August 27, 2003, please extend the period of time for response three months, to expire on February 27, 2004. Enclosed are a Petition for an Extension of Time and the requisite fee. Please amend the application as follows:

Remarks/Arguments begin on page 2 of this paper.

REMARKS

Favorable reconsideration of the instant application is respectfully requested in view of the following remarks. Claims 61, 62, 65 and 66 are pending in the application.

Rejection Under 35 U.S.C. §§ 101 and 112, First Paragraph

Claims 61, 62, 65 and 66 stand rejected under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph, as allegedly lacking a patentable utility. More specifically, the Action maintains the allegation that the specification does not support Applicants' assertion that polypeptides of SEQ ID NO:786 may be used for cancer diagnosis or treatment, since the specification does not provide evidence that polypeptides of SEQ ID NO:786 are overexpressed in lung tumor cells. The Action further asserts that data demonstrating that the polynucleotide of SEQ ID NO:69, which encodes the polypeptide of SEQ ID NO:786, is overexpressed in lung tumor tissue, is not sufficient to establish utility of the claimed polypeptide, since overexpression of a gene encoding a polypeptide does not translate directly into overexpression of the corresponding protein.

Applicants traverse this basis of rejection and submit that the Examiner has failed to establish a *prima facie* showing of lack of utility for the claimed invention under either 35 U.S.C. § 101 or 35 U.S.C. § 112, first paragraph. Instead, Applicants submit that the evidence demonstrating that polynucleotides encoding the claimed polypeptides are overexpressed in lung tumor tissue is clearly sufficient to establish the utility of the claimed invention, *e.g.*, in the diagnosis of lung cancer.

Applicants submit that when an applicant has asserted that a claimed invention is useful for any particular purpose and the assertion would be considered credible by a person of ordinary skill in the art, a rejection based on lack of utility should not be imposed. Utility Examination Guidelines, 66 Fed. Reg. 1099, 1098 (2001). Applicants submit that a skilled artisan would find credible the assertion that polypeptides of SEQ ID NO:786 are useful in the detection of lung cancer, based upon the disclosure that polynucleotides encoding said polypeptides are overexpressed in lung cancer. One of ordinary skill in the art is apprised of the fact that overexpression of an mRNA generally translates to overexpression of its encoded

polypeptide. Indeed, the Examiner, himself, acknowledged this in the Office Action mailed November 25, 2002, when he stated that he agreed with the statement that when a DNA is overexpressed, it is reasonable to expect that the corresponding protein will also be overexpressed. Applicants submit, in light of this understanding, that a skilled artisan would find the assertion that the polypeptides of SEQ ID NO:786 are useful in the detection of lung cancer entirely credible, given the evidence presented in the Declaration of Dr. Tongtong Wang, submitted May 27, 2003, which clearly demonstrates that polynucleotides of SEQ ID NO:69, which encode the polypeptide of SEQ ID NO:786, are overexpressed in lung tumor tissue.

Furthermore, Applicants point out that a *prima facie* showing of no specific and substantial credible utility must establish that it is more likely than not that a person skilled in the art would not consider credible any specific and substantial utility asserted by the applicant for the claimed invention. *Id.* Applicants submit that the Action has not established that it more likely than not that the skilled artisan would find Applicants' assertion that the claimed polypeptides are useful in the detection of lung cancer to lack credibility. On the contrary, Applicants submit that the skilled artisan would certainly believe it more likely than not that polypeptides of SEQ ID NO:786 are useful in the detection of lung cancer, given that the polynucleotides encoding said polypeptides are clearly overexpressed in lung cancer. Applicants also note that a statement of fact made by an applicant in relation to an asserted utility must be treated by the Examiner as true, unless countervailing evidence can be provided that shows that one of ordinary skill in the art would have a legitimate basis to doubt the credibility of such a statement. *Id.* Since one of ordinary skill in the art would find the instant assertion of utility to be entirely credible, and the Action provides no countervailing evidence indicating otherwise, the Action has not established a *prima facie* showing of lack of utility. Accordingly, Applicants respectfully submit that this rejection should be properly withdrawn.

Applicants further submit that Applicants are not required to provide evidence sufficient to establish that an asserted utility is true "beyond a reasonable doubt" or a matter of statistical certainty. M.P.E.P., 8th ed. § 2107.02, VII, *citing In re Irons*, 340 F.2d 974, 978 (CCPA 1965) and *Nelson v. Bowler*, 626 F.2d 853, 856-57 (CCPA 1980). Instead, evidence is sufficient if, considered as a whole, it leads a person of ordinary skill in the art to conclude that

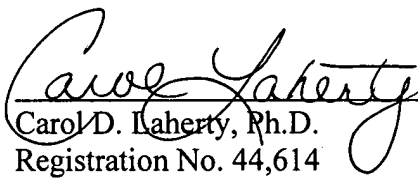
the asserted utility is more likely than not true. *Id.* Applicants submit that the skilled artisan would certainly find it more likely than not true that the claimed polypeptides are useful in the detection of lung cancer, since polynucleotides of SEQ ID NO:69 are overexpressed in lung cancer. The skilled artisan would readily conclude that it is more likely than not true that a polypeptide encoded by a polynucleotide overexpressed in lung cancer is, itself, also overexpressed in lung cancer, given the well-established relationship between nucleic acid and polypeptide expression. Thus, Applicants submit that the claimed invention clearly possesses patentable utility, *e.g.*, in the diagnosis of lung cancer, and respectfully request that this rejection be reconsidered and withdrawn.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicants submit that the claims remaining in the application are allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC


Carol D. Laherty, Ph.D.
Registration No. 44,614

CDL:jto

Enclosure:

Postcard

701 Fifth Avenue, Suite 6300
Seattle, Washington 98104-7092
Phone: (206) 622-4900
Fax: (206) 682-6031

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